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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,120	03/17/2000	Daphne Preuss	ARCD:P-01912US7	5601

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EXAMINER	
CHAKRABARTI, ARUN K	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/531,120	Preuss
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 8, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *132, 133, and 141-144* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *133 and 141-144* is/are allowed.

6) ☒ Claim(s) *132* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Specification

1. Claims 128-131, 134-140, and 145-146 have been cancelled. Claim 133 has been amended.

Claim Rejections - 35 USC § 112

2. ***The following is a quotation of the first paragraph of 35 U.S.C. 112:***

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

3. Claim 132 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 132 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid constructs and methods using the dicotyledonous Arabidopsis thaliana centromere and the starting plant cell Arabidopsis thaliana, does not reasonably provide enablement for making any transgenic plant with Arabidopsis thaliana centromere. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Court in re Wands, 8 USPQ2d 1400 (CA FC 1988) stated with regard to enablement that

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Here, the claim is broadly drawn to any plant and method of preparing any plant comprising any cell transformed with Arabidopsis thaliana centromere. However, the specification does not provide guidance commensurate in scope with this claim. The specification provides minimal guidance regarding any plant and method of preparing any plant comprising any cell transformed with Arabidopsis thaliana centromere. There is only one working example of Arabidopsis centromere mapping and characterization (Example 6). It is highly unpredictable whether or what other treatments would function in the context of preparing transgenic plants as Ebinuma et al (Proc. Natl. Acad. Sci., USA (1997 March), Vol. 94), pages 2117-2121) teaches, "(I) the selective agents have negative effects on proliferation and diffrentiation of plant cells, (ii) there is uncertainty regarding the environmental impact of many selectable marker genes, (iii) it is

difficult to perform recurrent transformation using the same selectable marker to pyramid desirable genes (Abstract)". It is therefore highly unpredictable whether other treatment strategies can be identified which meets this specific criteria regarding the successful introduction of economically valuable genes like centromeres into crop plants. Further, as indicated by Kriz et al.(U.S. Patent 6,307,123 B1) (October 23, 2001) identification of difficulties associated with plants possessing multiple transgenic copies including gene slicing, recombination and unpredictable inheritance (Page 63, lines 7-16), trial and error experiments must be carried out . This trial and error requirement is borne out because effects of random insertion of DNA into plant genome cannot be readily deduced, even where the genetic mapping and metabolic pathways are known. Further, each transfer of gene has unpredictable effects on metabolic function, and no general method for a priori selection of transfer of gene is presented. It would require a large amount of experimentation, potentially including the synthesis of millions of genes, in order to identify additional transgenic plants with the claimed functionality. Given the Wand's factors opposing the full scope of enablement including the limited teaching in the specification, the absence of sufficient working example, the teaching of unpredictability in the prior art, the unpredictability of the art, the breadth of the claim, and the large amount of experimentation needed, with only the skill level in the art being neutral towards enablement, it is concluded that undue experimentation is necessary to make and use the invention as broadly claimed.

35 U.S.C. 112, Written Description Rejection

4. Claim 132 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 1-21 which corresponds to the cDNA/genomic DNA encoding the Arabidopsis thaliana centromere sequences. Claim 132 is directed to encompass all plant gene sequences, sequences that hybridize to all plant gene sequences corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1-21, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious,"

and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which

nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1-21 and only starting plant Arabidopsis thaliana but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.).

Double Patenting

5. Claim 132 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 6,156,953. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 6 of U.S. Patent No. 6,156,953 basically and fundamentally teaches the instant method claim of preparing a transgenic plant cell by contacting a starting plant cell with recombinant DNA construct comprising an Arabidopsis thaliana centromere.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Allowable Subject Matter

7. Claims 133 and 141-144 are allowed.

Response to Amendment

8. In response to amendment, claims 133 and 141-144 are allowed.. However, 112 (written description and enablement) rejections and obviousness type double patenting rejection against claim 132 have been properly maintained.

Response to Arguments

9. Applicant's arguments filed on have been fully considered but they are not persuasive.

Applicant argues (page 29, last paragraph and page 30, first paragraph) that 112 (first paragraph) rejection should be withdrawn because the specification provides sufficient support and guidance to one skilled in the art such that the subject matter as defined in claim 132 can be readily practiced. This argument is not persuasive. It is highly unpredictable whether or what other treatments would function in the context of preparing transgenic plants as Ebinuma et al (Proc. Natl. Acad. Sci., USA (1997 March), Vol. 94), pages 2117-2121) teaches, "(I) the selective agents have negative effects on proliferation and diffrentiation of plant cells, (ii) there is uncertainty regarding the environmental impact of many selectable marker genes, (iii) it is difficult to perform recurrent transformation using the same selectable marker to pyramid desirable genes (Abstract)". This issue of unpredictability of preparing transgenic plants have never been discussed in the specification (as referred to by the applicant in Example 6 or pages 52-62 or pages 77 to 84 or page 20-21). It would require a large amount of experimentation, potentially including the synthesis of millions of genes, in order to identify additional transgenic plants with the claimed functionality. Given the Wand's factors opposing the full scope of enablement including the limited teaching in the specification, the absence of sufficient working example, the teaching of unpredictability in the prior art, the unpredictability of the art, the breadth of the claim, and the large amount of experimentation needed, with only the skill level in the art being neutral towards enablement, it is concluded that undue experimentation is necessary to make and use the invention as broadly claimed.

Applicant argues (page 30, second and third paragraph) to withdraw 112 (first paragraph, written description) rejection. This argument is not persuasive. The specification discloses SEQ ID NO: 1-21 which corresponds to the cDNA/genomic DNA encoding the Arabidopsis thaliana centromere sequences. Claim 132 is directed to encompass all plant gene sequences, sequences that hybridize to all plant gene sequences corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. Therefore, only SEQ ID NO: 1-21 and only starting plant Arabidopsis thaliana but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

Applicant argues to withdraw obviousness type double-patenting rejection (Page 30, last paragraph) . This argument is not persuasive. Applicant did not provide any reason to withdraw the double patenting rejection. Applicant argues that claim 132 and claims 1 and 6 of U.S. Patent No. 6,156,953 are not identical. The applicant is reminded that it is not statutory double-patenting rejection for which the conflicting claims have to be identical; it is obviousness type double patenting rejection. It was clearly stated in the last office action that claims 1 and 6 of U.S. Patent No. 6,156,953 basically and fundamentally teaches the instant method claim of preparing a transgenic plant cell by contacting a starting plant cell with recombinant DNA construct

comprising an Arabidopsis thaliana centromere. For making a proper obviousness type double patenting rejection, conflicting claims do not have to be identical word by word. See 37 CFR 1.130(b) and 37 CFR 3.73(b). In this case, conflicting claims are apparently obvious to any ordinary practitioner.

In view of the response to arguments, previous rejection of claim 132 is hereby properly maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. This phone number is going to change to (571) 272-0740 on and from January 13, 2004. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner,

December 29, 2003

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